A Strategy for the Development of New Biomedical Waste Management Facilities in Ontario

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AN INVITATION TO COMMENT

Interested individuals and groups are invited to comment on these proposals by making written submissions to the Waste Management Branch of the Ministry of the Environment. Waste Management Branch staff are also available to present and discuss these proposals at the invitation of interested groups. Comments and invitations may be sent to:

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1.0 INTRODUCTION

Managing biomedical waste in an environmentally and economically responsible fashion is an important issue facing Ontario today. The province's present lack of self-sufficiency in managing its biomedical waste, and the need to develop new disposal facilities, for the use of Ontario hospitals and other waste generators, are areas of concern that must be addressed. The Ministry of the Environment (MOE) and the Ministry of Health (MOH), in co-operation with the Ontario Hospital Association (OHA), have developed this strategy to address these areas of concern.

The following principles have been used to develop this strategy:

- Ontario should become self-sufficient in the management of its biomedical waste;
- new regional biomedical waste management facilities will be constructed and operated in the most cost effective manner, recognizing the financial constraints on the health care system;
- only biomedical and pharmaceutical wastes will be treated / disposed of in these new regional facilities;
- non-incineration technologies are to be used for the treatment of non-anatomical wastes where technically and economically feasible;
- incineration is to be used for anatomical and pharmaceutical wastes or where non-incineration technologies are not technically or economically feasible; and
- existing biomedical waste incinerators lacking best available air pollution control will be phased out as new regional facilities become operational.

2.0 BACKGROUND

The provision of human and animal health care and the associated activities of teaching, research, clinical and biological testing, as well as post-mortem care generates a unique waste stream commonly

Medical Wastes

referred to as medical wastes. It is estimated that Ontario generates approximately 150,000 tonnes of medical wastes annually. The majority (90 percent) of medical wastes are not hazardous and require no special handling prior to disposal in municipal solid waste landfills.

Biomedical Wastes

Less than ten percent (ie. 10,000 - 15,000 tonnes) of all medical wastes are considered to be hazardous enough to require special handling and treatment prior to disposal. These wastes, commonly referred to as "biomedical" wastes, include human anatomical wastes, infectious animal wastes, microbiological wastes, human fluid blood and blood products, sharps (needles, blades etc.), and wastes from patients with highly communicable diseases. Hospitals generate approximately 60 percent of biomedical wastes while other smaller generators such as laboratories, clinics, doctors, and dentists comprise the remainder.

Cost Effective Solution

Biomedical wastes are primarily generated by publically funded health care activities. The health care system in Ontario is increasingly under tight financial constraints. Any new biomedical waste disposal infrastructure must be designed to control the costs for public sector waste generators.

3R's

Where feasible, waste reduction, reuse and recycling programs should be applied to solid non-hazardous refuse generated in health care facilities. An Initiatives Paper entitled, "Regulatory Measures to Achieve Ontario's Waste Reduction Targets", dated October 1991, has previously been released for public discussion and details proposed 3R's targets and initiatives for the institutional sector which includes health care facilities. The regional strategy proposed in this paper addresses only the biomedical waste component where the application of waste reduction, reuse and recycling programs is limited due to public health considerations.

Self-Sufficiency

Ontario's overall waste strategy supports self-sufficiency in the management of waste. The current export of 60 percent of Ontario's biomedical waste to Quebec and the USA for disposal is not consistent with the strategy. Ontario needs to develop sufficient treatment and disposal infrastructure to achieve self-sufficiency in biomedical waste management.

The remaining 40 percent of Ontario's biomedical waste is burned in approximately 100 hospital incinerators across the province. Although the existing incinerators operate in accordance with the current air pollution regulations, these facilities lack modern air pollution control devices and as a result, there are environmental and public health

State of Existing Facilities

concerns regarding their continued operation. These incinerators rely on the dilution of pollutants rather than control at the bottom of the stack. The number of operating hospital incinerators is decreasing steadily as facilities are shut down voluntarily by hospitals or by request from the Ministry of Labour (MOL) or MOE. In many cases facilities are also used for the incineration of solid non-hazardous refuse generated in hospitals. While the existing hospital incinerators were designed for the disposal of both biomedical and general waste, this proposed strategy phases out existing incinerators when new facilities become operational. New facilities will not be permitted to burn solid non-hazardous refuse. This is consistent with MOE's ban on all future municipal solid waste incinerators announced in April, 1991.

Existing Disposal Technologies

Traditionally, the primary method of biomedical waste disposal has been incineration. Incineration is currently the only technology which has been approved by MOE for large regional biomedical waste management facilities. Although autoclaves are currently used to treat biomedical wastes at a few individual hospitals, the technology has not yet been approved for use in Ontario to treat larger quantities of waste in a regional facility.

Non-Incineration Disposal Technologies

Non-incineration technologies for biomedical waste treatment such as the autoclave, microwave, and shredding / disinfection (Hammermill) process have been developed and are being used in other jurisdictions in response to increased public concern with biomedical waste incineration. The Hammermill technology was recently tested by the Hospital Council of Metropolitan Toronto. This technology shreds and grinds biomedical waste to a granular size and simultaneously disinfects it with a dilute form of sodium hypochlorite (bleach). The autoclave process sterilizes waste in a vessel using saturated steam under pressure. The microwave process employs pre-shredding prior to the use of microwaves to thermally disinfect the waste. All these non-incineration technologies render the waste into a form acceptable for landfill disposal. These non-incineration technologies may be more cost-effective and environmentally acceptable alternatives. The MOE, MOH and OHA are currently assessing the available testing data on these new technologies and will develop performance and operating criteria for use in approving these new non-incineration technologies. The results of the Hammermill test undertaken by the Hospital Council of Metropolitan Toronto will be used in the development of criteria for shredding / disinfection technologies. Performance and operating criteria will be finalized by MOE, MOH and OHA before the implementation of this strategy.

Biomedical Waste

Currently biomedical waste is referred to as "pathological" waste in Ontario Regulation 309, under the Environmental Protection Act. This definition is not clear or precise in defining the waste stream, and is difficult to interpret and enforce. Biomedical waste generators have difficulty distinguishing which materials from health care facilities are regulated. This lack of clarity has resulted in wide-ranging definition interpretations and waste segregation practices throughout Ontario. A new biomedical waste definition has been prepared by MOE and is presented for review and comment (see 3.4).

3.0 PROPOSALS

The following proposals have been jointly developed by MOE, MOH and OHA to facilitate the development of an environmentally sound and cost effective biomedical waste management system in Ontario.

3.1 New Facilities

Regional Facilities

It is the position of the Ministry of Health and the Ontario Hospital Association that regional facilities offer a more cost-effective solution for biomedical waste disposal. On-site facilities in individual hospitals is now cost prohibitive. It is proposed that new facilities be shared regionally by hospitals and all other generators of biomedical waste. Disposal facilities should not rely solely on incineration and should employ a mix of technologies in the treatment of biomedical waste. The use of one central disposal facility for the Province is not preferred since biomedical wastes should be managed and disposed close to their point of generation.

Regional Biomedical Waste Management Plan

It is proposed that hospitals, as the primary waste generator, undertake a planning process in each regional area (Figure 1) with the objective of developing a biomedical waste management plan for the region. A regional planning committee comprised of hospital representatives and other stakeholders would be formed to develop the plan (see 3.2). This plan would include a proposal for the development of a biomedical waste treatment / disposal facility in each region. The necessary waste collection and transportation infrastructure requirements would also be outlined as part of the plan.

Many hospital administrators in Ontario feel that hospital owned and operated facilities are the most cost effective solution to dispose of biomedical waste. Other hospital administrators feel that hospitals should not be in the waste management business. All agree that

Private vs. Public Sector Operated Facilities

biomedical waste disposal must be operated in a cost-effective manner recognizing the funding constraints and limited resources available in the health care system. The protection and control of costs for biomedical waste disposal are of primary concern in establishing new facilities. The private sector is invited to express their views and ideas on how privately owned and operated facilities and waste transportation systems could be established which are cognizant of these public funding constraints.

Terms of Reference

Specific terms of reference will be provided by MOH, MOE and the OHA, for the regional planning committees to use throughout the planning process. These terms of reference are described in Section 3.3.

Funding

This discussion paper challenges stakeholders to put forward creative options for establishing regional biomedical waste management facilities and transportation systems which are cognizant of public funding constraints. Currently, MOH has the authority to fund 100 percent of capital costs related to hospital owned incinerators. MOH will review its funding policies in light of comments and proposals put forward during the public consultation. Funding will be made available to the regional planning committees for costs associated with developing the regional plans (consultants, public meetings, etc.).

3.2 Planning Process

Public Consultation

Public consultation has been identified as a key requirement for the development and implementation of this strategy. The planning process will provide a means for the concerns, needs, and values of others to be identified in advance of any decision to establish a biomedical waste management facility.

Regional Planning Committees

The regional biomedical waste management plan is to be developed by a committee comprised of representatives of the key generators of the biomedical waste stream. The province has been divided into 6 planning regions (Figure 1, based on the MOH planning regions), thus 6 regional committees will undertake the planning of biomedical waste facilities.

Committee Structure

Hospitals as principal generators of the waste stream will chair the committees and lead the planning process. Non-hospital waste generators and local municipal / regional governments and the public are proposed to be represented on the planning committees. The MOH, MOE and OHA will participate in an advisory capacity on the regional

Public Comments on Committee Structure

planning committees. Comments on the structure, membership and nomination of members on the regional planning committees are invited as part of these proposals.

Public Meetings

It is proposed that the regional planning committee would be responsible for initiating and chairing at least two public meetings. The first public meeting would be held at the outset of the planning process after the formation of the committee. The purpose of the meeting would be to introduce the public to the regional planning process and to outline how the planning process will be carried out in each region. At the conclusion of the planning process the planning committee would hold a second public meeting where the committee recommendations would be presented to the public.

3.3 Regional Planning Committee Terms of Reference

The terms of reference and committee budget would be provided to the regional planning committee by MOH, MOE and the OHA. A document outlining the final terms of reference will be prepared by MOH, MOE and the OHA after receiving and considering public comments on the overall proposal. The terms of reference would mandate the committee to develop a plan according to specific terms. The following planning principles and terms are proposed:

(i) use of non-incineration technologies for non-anatomical wastes where technically and economically feasible;

(ii) use of incineration technology for anatomical, pharmaceutical and microbiological laboratory wastes which present a significant biological hazard;

(iii) use of on-site non-incineration treatment may be considered as an option for an individual hospital if economically justified and supported by the committee;

(iv) non-hazardous hospital wastes (general refuse) are not to be disposed of in the new facilities;

(v) development of a plan for waste collection and transportation to the regional facility;

(vi) a workforce impact and adjustment planning analysis;

(vii) evaluation of the options for facility ownership and operation and, a cost / benefit analyses for each option considered;

(viii) a technical / environmental analysis of the options considered;

(ix) a plan for the phase-out of existing biomedical waste incinerators with no air pollution control technology ; and

(x) a public consultation program as outlined in this strategy.

Based on the needs of the region, the planning committee is to carry out a technical, environmental and economic analysis of alternatives. Issues of technology, performance and cost-effectiveness, facility size, site location, environmental impacts, and facility ownership must be addressed. Facilities may encompass a combination of technologies. The ownership and operation of the facility is to be proposed by the regional planning committee.

A final biomedical waste management plan should be submitted to MOH and MOE within one year of the committee start-up. The committee may contract a technical consultant to assist in the planning and evaluation of options.

3.4 Strategy Support

Information Needed

In order for the regional planning committees to undertake the task of developing a regional biomedical waste management plan, information regarding waste quantities, alternative technologies and biomedical waste disposal costs is required. MOE, MOH and the OHA will undertake the initiatives described below to support the implementation of the strategy.

Definition of Biomedical Waste

The current definition of pathological waste has been identified as requiring amendment of Regulation 309 under the Environmental Protection Act to better define the waste stream. A committee of stakeholders was struck in 1990 to develop a new biomedical waste definition. This new definition will assist generators in segregating their biomedical waste from general waste. A new definition is proposed and attached in Figure 2 . Regional facilities developed under this plan would be sized on the basis of the quantities of biomedical waste generated under the new definition. Review and comment on this new definition is invited as part of this consultation on the regional biomedical waste management strategy.

Public Comments on Definition

Waste Quantities Study

To determine waste generation rates based on the new biomedical waste definition, MOE, MOH and the OHA are undertaking a Waste Quantities Study. From this study, waste generation rates would be provided to the regional planning committees for use in sizing disposal facilities.

Regulatory Amendments

A number of provincial regulatory amendments such as Regulations 461/86 under the Public Hospitals Act and Regulation 309 under the Environmental Protection Act may be required to facilitate strategy implementation. Currently under the Public Hospitals Act, MOH may only fund 100 percent capital costs for the replacement of incinerators. Therefore, amendments to the Public Hospitals Act may be required to allow for the capital funding of non-incineration technologies for regional facilities. The current definition of pathological waste in Regulation 309 under the Environmental Protection Act will also be amended and renamed biomedical waste.

Operating and Performance Criteria

To support the use of non-incineration technologies, it is necessary to evaluate and provide information to regional planning committees and the private sector on the technical viability of alternative technologies. MOE, MOH and the OHA are currently reviewing commercially proven non-incineration technologies established in other jurisdictions. Available testing and performance data is being reviewed to assist in the development of operating and performance criteria. Autoclaves, microwaves, macrowaves, shredding / disinfection (Hammermill) and technologies are currently being reviewed as alternatives to incineration. MOE, MOH and the OHA will provide technical and operating criteria to the regional planning committees at the outset of the planning process for the non-incineration technologies approved.

To facilitate the implementation of the proposed strategy, it is necessary for MOE, MOH and the OHA to assess waste quantities and non-

incineration technologies. The current costs and practices related to biomedical waste management will be assessed to determine possible offsets in operating budgets of health care facilities. In addition, the capital and operating costs of each new technology must be determined. This information will be provided to the regional planning committees.

3.5 Environmental Approvals

EPA Approval

It is proposed that the technical approval mechanism for the facilities developed as part of the regional biomedical waste management plan be an approval under Part V of the Environmental Protection Act, regardless of whether the facility is a public, private or a joint venture. This approval involves a rigorous technical assessment of the proposal. Any undertakings whether private, public or a joint venture, proposed with the support of the regional planning committee and developed in accordance with the terms of reference principles, would be approved pursuant to the EPA approvals process. Any privately owned on-site treatment facilities would also be approved under the EPA. Any facilities accepting off-site waste and not developed in accordance with this plan may be designated under the Environmental Assessment Act (EAA). The need for the facility, a review of alternatives and type of technology chosen, the site selection process undertaken, and the extent of public consultation in the proposal will be considered by the Minister of the Environment in any EAA designation decision.

EAA Approval

Public Hearings

It is proposed that for approval under Part V of the Environmental Protection Act, there would be a mandatory public hearing where interested or affected parties may further express their support or concerns with the proposal. If a facility requires approval under the Environmental Assessment Act, interested parties can make submissions to the Minister of the Environment before the Minister accepts the environmental assessment, or refers the matter to the Environmental Assessment Board.

Fig. 1 Ministry of Health Planning Regions

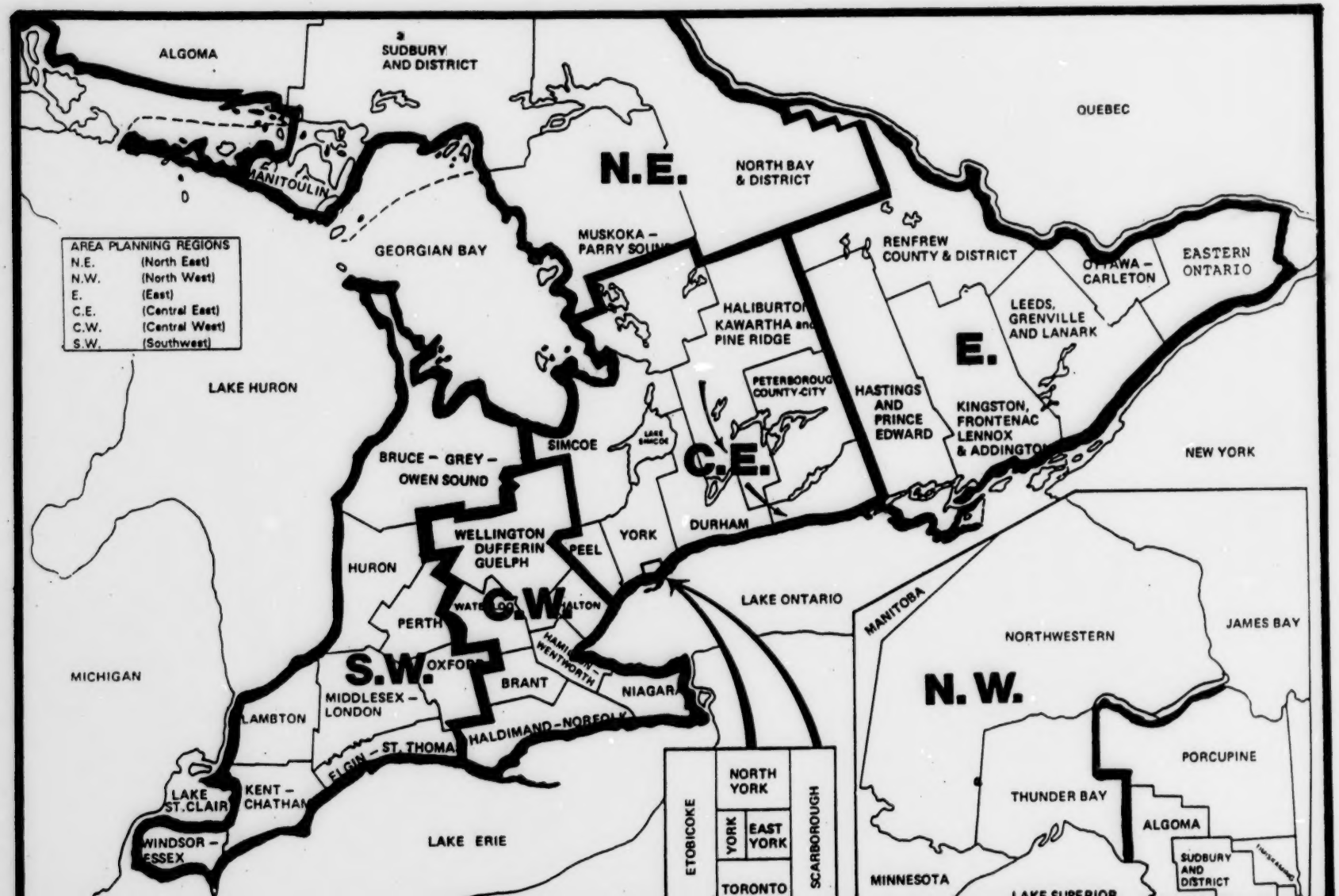

FIGURE 2 - PROPOSED DEFINITION OF BIOMEDICAL WASTE

March 24, 1992

Biomedical Waste means waste that is generated by human or animal health care facilities, medical research and medical teaching establishments, health care teaching establishments, clinical testing or research laboratories, mortuaries, funeral establishments, facilities involved in the production and testing of vaccines, and includes wastes generated from mobile health care;

limited to:

(a) human anatomical waste consisting of human tissues, organs and body parts, not including teeth, hair and nails;

(b) animal waste consisting of all tissues, organs and body parts, carcasses, bedding, fluid blood and blood products, items saturated or dripping with blood, body fluids contaminated with blood, body fluids removed during surgery, treatment, necropsy, or for diagnosis, unless determined by the a trained person designated by the generator that the waste does not contain the viruses and agents listed in Schedule 5A;

(c) non-anatomical waste limited to:

i) cultures, stocks or specimens submitted for microbiological analysis, live or attenuated vaccines, cell lines, human or animal cell cultures used in research, and, material that has come into contact with the above,

ii) human liquid blood or semi-liquid blood and blood products, items contaminated with blood that would release liquid or semi-liquid blood if compressed, body fluids contaminated with blood, and body fluids removed during surgery, treatment, autopsy, or for diagnosis, but not including urine and faeces,

iii) sharps including needles, blades, and glass or other materials capable of causing punctures or cuts;

(d) other waste not included above which:

(i) are deemed by a trained person designated by the generator to require special handling, or

(ii) have come into contact with an individual being treated or suspected to be infected with one or more of the viruses or agents listed in Schedule 5B;

but does not include waste that is:

i) from animal husbandry,
ii) domestic waste,
iii) controlled in accordance with the Health of Animals Act (Canada), the Dead Animals Disposal Act (Ontario), the Research for Animals Act (Ontario), Meat Inspection Act (Ontario), or the Meat Inspection Act (Canada),
iv) generated in food production, general building maintenance or office administration of the aforementioned facilities.

Ontario Regulation 309

Draft Schedule 5A

Agents of Biomedical Animal Wastes

Bacteria

Bacillus anthracis
Brucella - all species
Francisella tularensis, type A (biovar tularensis)
Mycobacterium avium; M. bovis (non-BCG strains); M. tuberculosis

Pseudomonas malleri; P. pseudomallei
Yersinia pestis

Viruses

Viruses are grouped within Family and / or Genus. Anthropod-borne viruses are identified with a double asterisk.

Arenaviridae
- Lymphocytic choriomeningitis virus, neurotropic strains

Bunyaviridae
- Unclassified Bunyavirus
  - Hantaan, Korean hemorrhagic fever and epidemic nephrosis viruses

Herpesviridae
- Gammaherpesvirinae
  - Genus Rhadinovirus: Herpesvirus ateles; Herpesvirus saimiri

Retroviridae
- Oncovirinae
  - Genus Oncornavirus C
    - Human T-cell leukemia/lymphoma virus (HTLV-I, HTLV-II,if cultured)
  - Genus Oncornavirus D
    - Mason-Pfizer monkey virus
    - Viruses from primates
- Lentivirinae
  - Human immunodeficiency viruses (HIV - all isolates if cultured)

Rhabdoviridae
- Genus Vesiculovirus
  - Piry
- Genus Lyssavirus

Rabies, street virus

Togaviridae
- Genus Alphavirus**
  - Eastern equine encephalitis virus
  - Chikungunya (recent isolates)
  - Venezuelan equine encephalitis (except Strain TC-83)

Unclassified Viruses
- Chronic infectious neuropathic agents (CHINAs)
  - Kuru, Creutzfeldt-Jakob agent (also listed under Level 2; level of the suspected agent depends on the nature of the manipulations and the amount of sera, bio/necropsy materials handled)

Arenaviridae
- Lassa, Junin, Machupo viruses

Bunyaviridae**
- Genus Nairovirus
  - Crimean-Congo hemorrhagic fever

Filoviridae
- Marburg virus
- Ebola virus

Flaviviridae**
- Tick-borne encephalitis complex, including -
  - Russian Spring-Summer Encephalitis
  - Kyasanur forest virus
  - Omsk hemorrhagic fever virus

Herpesviridae
- Alphaherpesvirinae
  - Genus Simplexvirus: Herpes B virus (Monkey B virus)

Poxviridae
- Genus Orthopoxvirinae
  - Variola
  - Monkeypox

Ontario Regulation 309

Draft Schedule 5B

Agents of "Other" Biomedical Wastes Requiring Special Handling

Bacteria

- Chlamydia psittaci
- Rickettsi
  - Coxiella burnetii

Viruses

- Arenaviridae
  - Lassa, Junin, Machupo viruses
- Bunyaviridae**
  - Genus Nairovirus
    - Crimean-Congo hemorrhagic fever
- Filoviridae
  - Marburg virus
  - Ebola virus
- Flaviviridae**
  - Tick-borne encephalitis complex, including -
    - Russian Spring-Summer Encephalitis
    - Kyasanur forest virus
    - Omsk hemorrhagic fever virus
- Herpesviridae
  - Alphaherpesvirinae
    - Genus Simplexvirus: Herpes B virus (Monkey B virus)
- Poxviridae
  - Genus Orthopoxvirinae
    - Variola
    - Monkeypox